

REMARKS

The present application includes pending claims 6-18, 20-21, 23, and 28-38. Claims 1-5, 19, 22, and 24-27 have been cancelled. Claims 6, 11, 14, 18, 20, and 21 have been amended. Claims 28-38 have been newly added. Support for amended claim 6, 11, 14, 18, 20 and 21 can at least be found at page 4 line 13, page 6 line 21, page 9 lines 25-26, Example 1, and original claims 18-19 and 21-22. Support for newly added claims 28-38 can at least be found on page 4 lines 22-23, page 7 lines 10-13 and 29-31, page 9 lines 15-16, original claims 5, 6, 10 and 11, and page 8 line 27 to page 9 line 8. Applicants submit that no new matter has been added. In view of the Remarks set forth below, Applicants respectfully submit that the Examiner's rejections have been overcome, and request allowance of pending claims 6-18, 20-21, 23 and 28-38.

35 U.S.C. §112 FIRST PARAGRAPH REJECTIONS

Claims 1-13, 18-24 and 26-27 are rejected under 35 U.S. C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. The Office action asserts that the term "entity" is vague and indefinite. The test for whether claim language is sufficiently definite to be patented is as follows:

The requirements for clarity and precision must be balanced with the limitations of the language and the science. If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 U.S.C. § 112, second paragraph) demands no more.

§ 2173.05(a) MPEP.

The relevant statute, 35 U.S.C. § 112 ¶ 2 (1988), requires that the claims "particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention." The operative standard for determining whether this requirement has

been met is "whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." See, *Beachcombers, International Inc. v. WildeWood Creative Products Inc.*, 31 U.S.P.Q.2d 1653, 1656 (Fed. Cir. 1994) (emphasis added) (quoting *Orthokinetics Inc. v. Safety Travel Chairs Inc.*, 806 F.2d 1565, 1576, 1 U.S.P.Q.2d 1081, 1088 (Fed. Cir. 1986)).

The term "entity" is defined in the specification at page 9, lines 25-32. As indicated there in the specification, "the entity to be decontaminated may be any physical item." As explained further, this term is intended to include solutions, devices, medical instruments and surfaces. Accordingly, applicants believe that when read in light of the specification, the use of the term "entity" in the claims is clear. However, in order to advance prosecution, the claims have been amended to recite "physical item" in place of "entity." It should be understood that as indicated at page 9 lines 25-32, the term "physical item" should be interpreted to include solutions, devices, medical instruments and surfaces. In view of the above remarks and amendment, the applicants respectfully request that the rejection of claims be withdrawn and the claims be reconsidered for allowance.

DOUBLE PATENTING REJECTION

Claims 1-27 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-24 of copending Application No. 11/977844. Applicants note that the copending application was filed with joint inventors and that it was filed after the filing of the instant application, and thus the claims of the copending application would not have anticipated or been obvious to the present application due to the later filing date. As this is a provisional rejection and neither application has claims in condition for allowance at this time, Applicants requests that the rejection be held in abeyance until such a time as the claims become allowable in both applications, at which time the applicants will consider filing a terminal disclaimer.

REJECTIONS UNDER 35 USC § 102

Claims 1-27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/54736 by Prusiner et al. (hereafter "Prusiner"). The Office Action alleges that Prusiner teaches processes, compositions and kits for decontaminating prion on surfaces. The Office Action alleges Prusiner discloses compositions comprising SDS and proteinase K to treat surfaces for prion contamination, in which these surfaces may be metal.

For a claim to be rejected based on 35 U.S.C. 102(b) as anticipated by a single prior art reference, each and every element in the claim must be found either expressly or inherently within that reference. § 2131 MPEP. Applicant submits that Prusiner does not expressively or inherently teach each and every element of the claimed invention. Prusiner does not teach or suggest a method of prion decontamination including the steps of contacting said physical item with a detergent, a first protease and a second protease, wherein said first and second protease are different and wherein steps of treatment occur simultaneously.

Prusiner discloses antiseptic compositions including a first agent (e.g., acids or mixtures of acids) that alters the pH of the composition to be less than a pH of 5.0 and a second agent or active agent that can inactivate prions at low pH. See, p. 3 lines 5-7, and 10-12. Suitable second or active agents disclosed include protein denaturants, inorganic salts, organic solvents, detergents and dendrimers. See, p. 3 lines 32-33. Prusiner does not teach or suggest a method of prion decontamination of a physical item comprising, among other things, "contacting said physical item with a first protease" or "contacting the physical item with a second proteinase" as in the presently amended independent claim 6. Further, Prusiner does not teach where the first and second proteases are different, or where the treatment with a detergent, a first protease and a second protease occurs simultaneously. Further, Prusiner does not teach or suggest a kit or composition containing "two or more proteases" as required by claims 18 and 21.

Further, the Office Action was mistaken regarding the context in which Proteinase K was used in Prusiner. Citing to page 39 lines 20-35, the Office Action alleges that Prusiner taught the use of a protease and SDS to inactivate prions. In Example 6 of Prusiner, ProteinaseK treatment was used for limited proteolysis of the proteins within the test samples after they were treated with antiseptic compositions for analysis by SDS page to identify the amount of PrP^{Sc} left within the samples. ProteinaseK was not part of the antiseptic composition. Therefore, the ProteinaseK was not being used as a decontaminating composition. Prusiner does not teach or suggest the use of proteases to inactivate prions, but as a diagnostic tool to measure the inactivation of prions by antiseptic compositions.

Therefore, Prusiner does not teach or suggest all the elements in claims 6, 18, and 21 for prion decontamination, and thus claims 6, 18 and 21 are novel and allowable over the disclosure of Prusiner. Further, dependent claims 7-17 which depend from claim 6, dependent claim 20 which depends from claim 18, claim 23 which depends from claim 21, and claims 28-38 which depend from claim 6 are also not anticipated by Prusiner for at least the reasons cited above, and are therefore allowable.

CONCLUSION

In view of the arguments provided herein, Applicants believe that the pending rejections under 35 U.S.C. § 112 paragraph 2 and 35 U.S.C. § 102(b) have been overcome. Applicants respectfully submit that claims 6-18, 20-21, 23, and 28-38 are therefore in a condition for allowance.

Applicants include the fee associated with the two-month extension of time with the filing of this Response. The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

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Respectfully submitted,

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